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Guest Editorial

Reflections on Risk Assessment

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More than 10 years have passed since Chauncey Starr published his famous paper in *Science* in which he proposed that the assessment of risk posed by technology might be amenable to quantitative analysis.[1] Many papers and books have since appeared that have analyzed and reanalyzed the assessment of risk from the points of view of the technologist, the systems analyst, the decision analyst, the psychologist, and the philosopher. Though I do not claim intimate acquaintance with this literature, I have read enough of it to convince me of the usefulness both of careful analysis of the way in which risks are actually assessed, as well as more abstract study of underlying methodologies. I therefore welcome the new journal, *Risk Analysis*, where practitioners of the art of risk assessment can exchange their views and results.

I use the word "art" intentionally: I can hardly conceive of large parts of risk assessment becoming a science. This is not to say that careful analysis of underlying assumptions that go into risk assessment is fruitless; or that careful observation of damage caused by large insults is not a part of science. But there are, and will always be, strong trans-scientific elements in risk assessment. We should be prepared to recognize these, and accept them.

William W. Lowrance in his paper, "The Nature of Risk," identifies six classes of hazards: (1) infectious and degenerative diseases; (2) natural catastrophes; (3) failure of large technological systems; (4) discrete, small-scale hazards; (5) low-level, delayed-effect hazards; and (6) sociopolitical disruptions.[2] Most of risk assessment today is focused on (3), failure of large technological systems, and on (5), low-level delayed-effect hazards. Both of these I would classify as "rare events" because in neither instance is it practical to build enough nuclear reactors or DC-10's to observe the failure rate, or to conduct experiments on a sufficiently large scale to actually see a response at very low dose. To be sure, in the case of DC-10's and reactors, event-tree analysis can yield estimates of overall failure rates; but these rates are extremely small. Thus the most powerful method of science—experimental observation—is inapplicable to the estimation of overall risk in exactly those instances where public policy most demands assessment of risk. This intrinsic uncertainty is reflected in the bitter controversy that rages over the safety of nuclear reactors, or over the use of the strict linear hypothesis in setting standards for low-level exposure to carcinogens and mutagens.

Much of *Risk Analysis* will be devoted to refining and quantifying our estimates of risk in situations where exposures are large and quantification is possible—where risk analysis is indeed part of science. But if one concedes that in the more important cases of small exposures or rare events there are essentially unknowable elements in risk assessment, we are still left with the practical problem of setting standards of acceptable risk. How do we decide what is an acceptable risk in circumstances where the assessment of risk is beyond the proficiency of science, that is, is trans-scientific?

Arbitrary elements obviously must creep into standard-setting when the risks themselves are so hard to assess. But, if we are honest, we must admit that even when the risks *can* be quantified, the setting of standards is intrinsically a political act—that is, the standards themselves must in final analysis be arbitrary, or must invoke some principle that goes beyond mere quantification of the risk. Thus we now believe that the 55-mph speed limit saves several thousand lives per year. Why not reduce the speed

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limit further since even more traffic fatalities would thereby be avoided? We chose 55, rather than 50 or 60 mph, not by applying an elaborate cost-benefit calculus, but by a political process.

No manipulation of cost-benefit calculus can obscure this essential arbitrariness in setting standards of acceptable risk, even when the risk itself is accurately known. Would it not be more straightforward, then, to invoke some strategy other than cost-benefit analysis upon which to base standards, especially in those situations where the risks are unquantifiable?

One such possibility is the invocation of a *de minimis* principle: Below a certain level of exposure or insult, we shall simply accept whatever residual risk is incurred; we only assure ourselves that the risk is "small." The arbitrariness lies then in deciding what is a *de minimis* exposure, whether to radiation, or chemicals, or other insult, that results in a "small" risk.

Where the insult is a manmade addition to an existing background, as is the case for radiation, an exposure "small" compared to the natural background seems to me to be a sensible standard, much more sensible than a standard based on futile attempts to compute the number of casualties caused by the existing and ineradicable background and then striking an arbitrary balance between cost and benefit.

The issue hangs around the definition of "small" compared to natural background. Here I am taken by H. Adler's suggestion that "small" be defined as the standard deviation of the natural background.[3] For low LET radiation, in the continental United States, this amounts to about 20 mr/yr: This is close to the 25 mr/yr limit set by the Environmental Protection Agency for allowable exposure to effluents from the nuclear-fuel cycle.

The essence of this approach to setting an acceptable *de minimis* level is comparison of risks—in this case the risk of manmade radiation compared to background radiation. We make the implicit assumption that background radiation poses an acceptable risk, whatever that risk may be (and which we do not try to quantify). An exposure that is small compared to this is *a fortiori* acceptable. Can this principle be extended to risks for which there is no natural background? A possibility that deserves consideration is first to evaluate the risk, say of a chemical for which a standard is required, against the risk of radiation at sufficiently high levels of exposures that the risks of each can be unequivocally determined. One could then invoke a principle of consistency: The allowable exposure to the chemical in question should cause no more damage than that caused by the *de minimis* level previously set for radiation. The damage caused by the *de minimis* level for radiation and for the chemical in question is determined by the linear hypothesis. To be sure, this scheme invokes the linear hypothesis against which I have often inveighed: but it invokes it in "weak" form—not as an estimator of damage, but as a means of comparing two, essentially unknowable, risks.

Though I find the previous proposals attractive in principle, and I sense that *de minimis* is being talked about in the standard-setting community, I am left with an uneasy feeling that such proposals leave out an essential reality: that standards must always be set in a social matrix. Where the standard setter finally comes out is inevitably influenced by the social milieux in which he operates. Can the social structure in which standards must be set actually be exploited to arrive at more sensible standards? The Soviet Union and the United States represent the two extreme social structures: a centrally planned system and a market system. On the whole, standards set in the Soviet Union for, say, radiation exposure, resemble those in the United States; the glaring exception is microwave exposure levels which, in the Soviet Union, are considerably lower than in the United States. On the other hand, U.S. nuclear reactors have been enclosed in containment vessels since the beginning; Soviet reactors until recently have had no containment domes. Thus it would not be easy to attribute to the one system or the other a greater concern for the public's safety.

This flies in the face of some currently fashionable doctrine: Socialist systems, not concerned with profit, are supposedly more likely to err on the side of safety than are capitalist societies. That this is not manifestly the case may suggest that an important, and insufficiently recognized sanction exists within our market society to ensure a balance between risks and benefits, between costs and safety.

The risk-benefit balance is really a 2×2 risk-benefit matrix with four elements: public risk, public benefit, private risk, private benefit (Fig. 1). For each technology a risk-benefit matrix can be constructed. For example, in the case of nuclear reactors, the public risks are radiation hazard and proliferation; the public benefit is abundant energy. The private risk is the financial loss, even failure, of the organization responsible for the reactor. (The survival of

	Risks	Benefits
Private	Financial Loss, Company Survival	Profit, Growth of Company
Public	Radiation Hazard, Proliferation	Abundant Energy

Fig. 1. Risk-benefit matrix for reactors.

the Metropolitan Edison Company was placed in jeopardy by the events at Three Mile Island.) The private benefit is profit.

The risk-benefit philosopher (if I can use this description) or those who claim to speak in the public interest, are concerned with the public risks and public benefits. For them a decision as to when a nuclear reactor is safe enough amounts to weighing the risk of excess radiation against the benefit of abundant energy—say reduction in import of oil. The whole theory and philosophy of regulation of risks is, I believe, based on the assumption that only these public risks and benefits are germane to answering the question, "What is safe enough?"

This conventional view neglects the very real, and powerful, sanctions imposed on a manufacturer by the private risks he incurs if his products fail. The heaviest loser at Three Mile Island was the utility and the manufacturer responsible for the reactor. One can expect reactors to be built and operated more safely in the future because, as a result of Three Mile Island, every actor in the nuclear enterprise realizes that unless he operates safely, he can be put out of business. This is powerful medicine indeed: The balance between safety and cost (which is the underlying balance in all setting of standards) will surely be moved toward safety as a result of the accident at Three Mile Island.

Can the market system by itself, without government intervention, be counted upon to strike a proper balance, to maintain public risk at an acceptable level? The simple answer is no—government, that is, nonmarket interventions—will always be needed. But if the *costs* of inadequate safety could be sufficiently internalized—i.e., if designers and managers of enterprises that create and market products or devices that pose risk, could be made sufficiently aware of the private risks they incur if they draw the *private* risk-benefit line incorrectly, I should think we would rather automatically achieve a pragmatic balance between risk and benefit that would be an important adjunct to the balance we now achieve by direct intervention. I do not want to minimize the difficulties that lie in the way of internalizing the costs of inadequate safety. Clearly an informed and concerned citizenry is required if the private sector is to receive signals that are strong enough to affect the balance sheet significantly.

The issue I raise is not part of science, yet it seems to me to be very relevant, if not to the analysis of risk, then to the more practical, related question of how to set standards of acceptable risk. I hope that *Risk Analysis* continues to make room in its pages for dialogue on risk policy. Perhaps more important, I hope those who work on the scientific side of risk analysis will interest themselves in the formulation of policy that flows from their scientific findings.

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